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EXAMINER

COE, SUSAN D

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 23

Application Number: 09/367,481
Filing Date: August 13, 1999
Appellant(s): FUSHIKI ET AL.

Eugene C. Rzucidlo
For Appellant

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EXAMINER'S ANSWER

This is in response to the appeal brief filed February 21, 2002.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

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(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Appellants' brief includes a statement that the claims stand or fall together.

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

US 3,764,692	LOWENSTEIN	10-1973
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US 5,536,516	MOFFETT et al.	7-1996
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McCarty, M.F. "Inhibition of Citrate Lyase May Aid Aerobic Endurance" Medical Hypotheses (1995), vol. 45, pp. 247-254.

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(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 24-31, 40, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 3,764,692 in view of US Pat. No. 5,536,516 and McCarty (Medical Hypotheses (1995), vol. 45, pp. 247-254) for the reasons of record set forth at pages 6 and 7 of the Office action of January 14, 2000.

US '692 is drawn to an orally administered composition for treating obesity. The active ingredient of the composition is (-) hydroxycitric acid derived from the fruit of *G. cambogia*. The (-) hydroxycitric acid can also be used in lactone form or as a pharmaceutically acceptable salt such as the sodium or potassium salt of the acid (column 1, lines 27-46; column 2, lines 1-5; and claims 1 and 7).

The hydroxycitric acid free acid, salt, and lactone can be administered with any pharmaceutically acceptable carrier such as water, gelatin, starch, or vegetable oil (see column 2, lines 26-35). All of these carriers are considered food.

While this reference teaches orally administering the claimed (-) hydroxycitric acid and derivatives, it does not teach extracting the (-) hydroxycitric acid from *G. indica* or *G. atroviridis*.

US '516 teaches that free acid and lactone forms of hydroxycitric acid can also be extracted from the fruit of *G. indica* and *G. atroviridis* and *G. cambogia* (see column 1, lines 7-10). These compounds are used for oral administration. This disclosure shows that the presence of orally administrable hydroxycitric acid in extracts from *G. indica* and *G. atroviridis* was known in the art at the time of the invention. Based on the disclosure by US '516 that

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hydroxycitric acid can be extracted from *G. indica* and *G. atroviridis* as well as the *G. cambogia* disclosed by US '692, a person of ordinary skill in the art would have had a reasonable expectation that hydroxycitric acid could be successfully extracted from *G. indica* and *G. atroviridis*. Therefore, the artisan of ordinary skill would have been motivated to use *G. indica* and *G. atroviridis* as a source of hydroxycitric acid based on the disclosure by US '516.

US '692 and US '516 teach hydroxycitric acid compositions; however, they do not teach administering the compositions for increasing endurance during exercise. McCarty discloses that hydroxycitric acid compositions from garcinia used for inducing weight loss may also be used to increase endurance (see page 250). The hydroxycitric acid compositions of US '692 and US '516 are both used for reducing body weight. McCarty also teaches that hydroxycitric acid may increase endurance during exercise and aid in liver-glycogen loading prior to prolonged exercise (see page 250). McCarty's disclosure shows that hydroxycitric acid compositions administered for weight loss can also be used to increase endurance during exercise. Based on McCarty's disclosure, a person of ordinary skill in the art would have had a reasonable expectation that the hydroxycitric acid compositions taught in US '692 and US '516 would have been useful in increasing endurance. Therefore, an artisan of ordinary skill would have been motivated to use the hydroxycitric acid compositions taught by US '692 and US '516 in the method taught by McCarty.

(11) Response to Argument

The appellant argues that an artisan of ordinary skill in the art would not be motivated to administer hydroxycitric acid (HCA) as taught by US '692 and US '516 to increase exercise endurance based on the teaching of McCarty. The appellant argues that the examiner's use of

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McCarty to provide motivation for administering HCA to increase exercise endurance is based on “nothing more than the Examiner’s subjective belief” (page 9, section B of the appeal brief). The appellant also argues that the hypothesis of McCarthy to administer HCA to increase exercise endurance is “groundless.” However, the examiner disagrees with these assertions by the appellant. McCarthy provides clear reasoning and support as to why HCA would be able to increase aerobic endurance. As support for this hypothesis, McCarthy explains that during prolonged exercise muscles uptake glucose at a large rate. This increased need for glucose must be met by an increased amount of available glucose in the blood. The increased amounts glucose are provided by the liver through gluconeogenesis (see paragraph bridging pages 247 and 248). McCarthy contends that gluconeogenesis is promoted by HCA because HCA is an inhibitor of the enzyme citrate lyase. By inhibiting citrate lyase, HCA promotes gluconeogenesis which allows an increased amount of glucose in the blood. The increased amount of glucose available for uptake by the muscles would allow for increased periods of exercise. In addition, HCA may promote glycogen loading before exercise (see page 250, section “Citrate lyase inhibition may promote gluconeogenesis”). Thus, while McCarthy does not provide any direct experimental evidence to support the hypothesis that HCA increase exercise endurance, McCarthy does provide clear reasoning based on what was known in the art at the time of the invention. Based on this reasoning by McCarthy, McCarthy is considered to teach that HCA increases exercise endurance. On reading McCarthy, a person of ordinary skill in the art would reasonably expect that HCA could be administered to increase exercise endurance. Therefore, an artisan of ordinary skill would be motivated to administer HCA compositions, such as those taught by McCarthy, US ‘516, and US ‘692, to increase exercise endurance.

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To refute this teaching by McCarty, the appellant relies on two main points. Firstly, the appellant argues that a person of ordinary skill in the art would question the conclusions drawn by McCarty based on Dohm et al. (J. App. Physiol. (1983), vol. 55, no. 3, pp. 830-833). The appellant contends that Dohm teaches away from McCarty because Dohm teaches that lower glycogen levels in the liver promotes aerobic endurance. Based on this teaching, the appellant states that McCarty's hypothesis that increased gluconeogenesis increases exercise endurance is groundless. The examiner disagrees for several reasons. Firstly, Dohm is not examining the effects of HCA on exercise. In fact, Dohm does not mention HCA at all. Therefore, Dohm is not directly relevant to the process as claimed or to McCarty's disclosure. In addition, Dohm is examining a different metabolic process from McCarty. The rats studied by Dohm show increased endurance after the rats have been fasted for 24 hours. The starved rats are able to run for longer than the rats that have been fed. Therefore, Dohm shows that fatty acids may be a better source for aerobic energy than glycogen. It is known in the art that the metabolic pathway that uses fatty acids for energy is different than the pathway that uses glycogen. Thus, Dohm is examining a different source for increased energy. The two pathways are distinct. Therefore, an artisan of ordinary skill would not look to Dohm to refute the hypotheses of McCarty especially since Dohm is not cited by McCarty.

However, even if an artisan did read Dohm in relation to McCarty, a person of ordinary skill in the art would be more likely to dismiss the conclusions of Dohm than those of McCarty. If one were to totally accept and follow the teaching of Dohm, Dohm would be suggesting that it is preferable for an athlete to fast for 24 hours before a marathon. This is in direct contrast to what is well known in the art. It is extremely well known that before competitions that require

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endurance, athletes practice the energy promoting activity of carbohydrate loading.

Carbohydrate loading leads to increased amounts of glycogen in the liver that is then available for energy during exercise (see McCarty at page 247, second column, first paragraph). McCarty states that HCA may aid in this process. Therefore, an artisan of ordinary skill would not be lead away from the teaching by McCarty based on Dohm because Dohm examines a different metabolic pathway and because Dohm comes to a conclusion that is in direct contrast to well known practices in the art.

The appellant's second main point to refute McCarty is that McCarty has an incorrect understanding of the function of HCA. The appellant contends that a person of ordinary skill in the art would recognize that McCarty's understanding of the function of HCA is incomplete, and, based on this understanding would dismiss McCarty's conclusions about the ability of HCA to promote endurance. To support this assertion, the appellant cites Brunengraber et al. (Eur. J. Biochem. (1978), vol. 82, pp. 373-384). The appellant states that Brunengraber teaches that any glucose produced by HCA would not be available as an energy source because the glucose could not be utilized by the citric acid cycle. However, the conclusions drawn by Brunengraber are not as clear cut as the appellant states. Brunengraber shows that the effects of HCA on metabolism in the liver vary based on several different factors. Brunengraber does not draw any clear conclusions on the ability of HCA to promote gluconeogenesis and if any glucose produced would be available as an energy source. Most importantly, Brunengraber does not investigate any effects that HCA has on increasing exercise endurance. Therefore, Brunengraber does not directly or clearly refute any hypothesis made by McCarty. Thus, Brunengraber is not considered to teach away from McCarty.

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In addition, the appellant submitted a declaration by an inventor, Dr. Fushiki. This declaration was submitted with appellant's response filed May 10, 2001. The declaration reiterates the arguments made in the response filed May 10, 2001. The declaration was considered by the examiner (see bottom of page 2 of the Office action of December 3, 2001). The declaration states the reasons why the inventor believes that a person of ordinary skill in the art would not be motivated to rely on McCarty based on the Dohm and Brunengraber references. These arguments were answered fully by the examiner in the Office action of December 3, 2001 and are answered in this Examiner's Answer. The declaration did not provide any data to support the arguments made by the appellant in the responses by the appellant and in the declaration itself. Without such data to support appellant's arguments, the declaration was a reiteration of arguments that were already of record. Thus, the conclusions in the declaration were not considered persuasive by the examiner for the reasons of record. Therefore, the examiner did not make an error in the consideration of the declaration as contended by the appellant. The declaration was given full consideration and full appropriate weight. The arguments were answered in that they were a reiteration of the arguments made in appellant's responses.

For the above reasons, it is believed that the rejections should be sustained.


Respectfully submitted,

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May 1, 2002

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